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All authors contributed to drafting the manuscript and approved the final version.

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STATEMENT OF CONFLICT OF INTEREST

None

ETHICAL APPROVAL

Ethical approval for this study was not required because the survey was conducted with publicly-available data.

Keywords: risk; disclosure; risk assessment; nonprescription drugs; self-medication; health knowledge, attitudes practice; risk management; self-care.

Word Count: 3197

Public risk perception of non-prescription medicines and information disclosure during consultations: a suitable target for intervention?

ABSTRACT

Objective

Optimisation of nonprescription medicine (NPM) supply from community pharmacies could reduce demand on other healthcare providers, including general practitioners and emergency department personnel. Outcomes can be maximised if patients disclose relevant information e.g. concomitant medication, during pharmacy-based consultations. Strategies to promote information disclosure are needed. This study used the Psychometric Paradigm of Risk to explore whether the public's risk perception of NPMs was associated with information disclosure.

Methods

This national, cross-sectional population study used a random sample of 3000 adults (aged ≥18 years) from the Scottish Electoral register. Postal questionnaires collected data on risk perceptions, information disclosure and demographic information. Exploratory factor analysis was used to determine constructs to which the risk questions could be grouped. Factors were scored and the scores compared across demographics.

Key Findings

Just over half (57%) of the 927 respondents perceived NPMs to be associated with low general risk. For 19 of the 23 statements (83%), respondents indicated general agreement i.e. low risk perception of OTC medicines. Individuals with higher risk perception of NPMs were less likely to disclose information during consultations compared with respondents with lower risk perception.

Conclusion

There is general low public risk perception of NPMs. Individuals with higher risk perception are less likely to disclose information. Interventions that raise risk perception are unlikely to enhance the safe and effective supply of NPMs.

INTRODUCTION

Nonprescription medicines (NPMs) enable patients to manage conditions without recourse to health-seeking from high cost settings e.g. general medical practices, emergency departments. The consequences of inappropriate NPM use are often explored using indirect measures because traditional methods of pharmacovigilance are less applicable due to the lack of documentation in patients' medical records. Previous research demonstrated that 6.5% of all emergency hospital admissions were due to adverse drug reactions (ADRs) and that the majority of these were associated with non-steroidal anti-inflammatory (NSAIDs), aspirin in particular [1]. Most NSAIDs (e.g. ibuprofen) implicated in these admissions are available as NPMs in the UK; low dose aspirin (75mg) is widely available internationally and contributed to the majority of NSAID-related harms primarily gastro-intestinal haemorrhage. A recent Dutch study confirmed the use of NSAIDs by "high risk" patients and reiterated the need for patients to be warned about the risks of these medicines [2].

Evidence suggests the sale/supply of NPMs from community pharmacies is sub-optimal irrespective of country, product or health condition [3, 4]. Managing NPM consultations is complex; pharmacists and their staff are often required to make recommendations based upon incomplete symptom information, other medical conditions, other medications being used, as well as the health status of clients. The way in which clients "present" during consultations varies with some requesting a specific product (hereafter referred to as 'direct product request'), while others seek advice to address symptoms or clinical condition. Direct product requests, which account for the majority of NPM consultations, are less likely to result in an appropriate outcome i.e. supply of medicines consistent with best evidence, compared with advice-seeking requests [5]. This variation has been attributed to low rates of information disclosure during product requests [6].

Individual's perceptions of the benefits and risks of medicines are likely to influence their treatment decisions. For prescribed medicines, there is ample evidence that patients are less likely to engage appropriately if they believe there are risks; a recent meta-analysis found that patients with more concerns were less likely to adhere to the medicines regimen [7]. For NPMs, one study reported that 40% of Americans believed that NPMs were too weak to cause any real harm, and one-third took more than the recommended dose, believing it would increase effectiveness [8]. Whilst there has been some exploration of public perception of risk of NPMs [9-11], only one study to date has adopted a theoretical approach to exploring these beliefs [12], which applied the Theory of Planned Behaviour to exploring low-to-middle income women in Mexico's risk perception of cold and flu remedies. Whilst the majority of these studies have sought to explore sources of information used by the public to increase their knowledge of these medicines as a means of mitigating risk, none has explored the effect of risk perception on information disclosure during consultations.

It is therefore important to understand individual and public risk perceptions of medicines so that interventions can be targeted to promote safe and effective use. The psychometric paradigm [13], proposes that the explanatory power of risk perception is clearer when scores are disaggregated to show differences between people separately from differences between hazards. The psychological paradigm of risk [13] involves asking individuals to assess the relative risk associated with specific items, hazards or behaviours. Within this paradigm, individuals make quantitative judgements of the risk associated with different hazards and their desired level of regulation for each of these hazards.

The purpose of the present study was to:

- Describe public risk perceptions of NPMs

- Explore the association between general risk perception, specific components ofrisk perception and information disclosure behaviour during consultations for NPMs

Our hypothesis was that a lower risk perception of NPMs would be associated with reduced information disclosure information during consultations for NPMs.

METHODS

Design and Participants

A cross-sectional population survey was conducted in 2008 to determine factors associated with buying NPMs and giving information to pharmacy staff when buying "pharmacy medicines". The questionnaire was informed by the Theory of Planned Behaviour (TPB) [14]. This theory identifies important determinants of voluntary behaviours such as information giving. The term "Pharmacy medicines" was used for NPMs and was defined as "medicines that can be bought from pharmacies (chemists) without a prescription". The TPB proposes that behaviour is predicted by behavioural intention which in turn is influenced by Perceived Behaviour Control (PBC) (i.e. whether the behaviour is difficult or easy to perform), subjective norm (SN) (i.e. whether important others consider the behaviour to be important) and attitude (ATT) towards the behaviour (i.e. whether engagement with the behaviour will achieve valued outcomes) (Figure 1).

Using the Scottish Electoral register, a random sample was taken, stratified by sex. Adults aged ≥18 years (one per household) and those not registered with the Mail Preference Service were approached. Postal questionnaires were mailed to 3000 participants with a 2:1 female to male ratio to reflect the population of people purchasing NPMs from community pharmacies [15, 16]. The results presented here relate to respondents' risk perceptions regarding NPMs.

Questionnaire Content and Administration

The questionnaire collected the following information:

- Risk perceptions of NPMs. Risk was defined as *"a situation that could expose you to harm or have an unpleasant outcome".*
- Predictors (based on the Theory of Planned Behaviour, [14, 17] of buying products and giving information using measures of attitudes and perceived behavioural control reported elsewhere [6].
- Demographic characteristics.

A reminder letter was sent after two weeks and included a reply paid envelope. A second reminder letter, non-reply form and reply paid envelope were sent to non-responders after a further two weeks.

Pharmacy medicines and risk

Respondents were asked "in general how much risk do you think there is when using a pharmacy medicine" and was measured on a scale from one to seven, anchored by descriptive terms at extreme values only (1=low risk, 7=high risk). They were also asked to state their agreement about the risk of 23 additional items related to NPMs, derived from the psychometric paradigm attributes [13]. Agreement was measured on a 7-point scale (1=strongly agree; 7=strongly disagree) where agreement equates to low risk perception. Information disclosure ('giving information') was explored using constructs from the TPB [6]. Respondents were also asked an open question to name the NPMs which they considered to be associated with least and most risk.

Data Management and Analysis

Data were entered and analysed in SPSS version 20 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY). Demographics summarised using frequency and percentage for categorical variables, mean and standard deviation for age. Risk questions were summarised using number and percentage responding in each category of the 1-7 scale and mean agreement was calculated [18]. Two questions were reverse coded to align the interpretation (*It is not possible to overdose with pharmacy medicines; There are no risks associated with using pharmacy medicines).* Two categories of risk perception were derived: low (1-3), high (4-7). The neutral category (4) was included within high risk, so that any observed effect would be a conservative estimate of association.

Exploratory factor analysis was undertaken to determine whether responses could be grouped by constructs of risk. A correlation matrix of responses to the 23 specific risk questions was obtained. An a priori decision was made to exclude a question from the factor analysis if its correlation coefficients with all other questions was <0.2 [20]. The Kaiser-Meyer-Olkin (KMO) test [19] and Bartlett's test of sphericity [20] were conducted to test whether there was sufficient common variance and correlation to carry out the factor analysis. According to convention [21], a minimum level of 0.5 was used for the KMO test to indicate sufficient common variance. Cattell's scree plot [21] and Kaiser's eigenvalue [19] criterion were used to determine the number of factors to extract. Factors were extracted using principal components analysis rotated with varimax rotation [22]. Items contained within factors were limited to those with a factor loading of >0.4 [20]. To generate a factor score the average of the identified statements within that factor was calculated for each respondent. For example, for a factor containing 4 items (a_1, a_2, a_3, a_4) the score was given by the following equation: $score = (a_1 + a_2 + a_3 + a_4) / 4$. Higher scores indicate higher perception of risk. Univariate tests (Mann Whitney or Spearman's rank correlation) were performed to determine the relationship

between factor scores and respondent demographics on information disclosure. Multiple linear regression using forward selection (entry $p<0.05$) identified which demographics were predictive of factor scores.

Sample size

The factor analysis conducted for this study was based upon 21 questions resulting in six factors. The recommended minimum sample size for conducting factor analysis using these parameters is 900 [23].

Ethical approval

Ethical approval for this study was not required because the survey was conducted with publicly available data.

RESULTS

RESPONDENT CHARACTERISTICS

The demographic characteristics of the 927 respondents are shown in Table 1. Respondents were aged between 19 and 96 years (mean 52.3, SD 16.1), three quarters of whom were female, almost all of whom were of white ethnic origin. The majority (69%) were married/ living with partner with 48% having no formal qualification or only school-level education. Just over half reported their health to be very good or excellent. Nearly half (49%) had used a pharmacy in the previous 14 days and 43% had bought a NPM in the previous month.

Public Perceptions of Risk of NPMs

In response to the general risk question, over half the respondents indicated there was low risk to using NPMs (57.0%), with 23.9% remaining neutral and 19.0% indicating high risk

response. The majority (19/23) of statements had a mean score <4 on the 7 point scale indicating general agreement with these statements i.e. low risk perception of OTC medicines. The four statements with which respondents tended to disagree were: *"the risks associated with using pharmacy medicines are likely to be fatal", "there is more risk involved with using pharmacy medicines than there was 10 years ago", "people who use pharmacy medicines know precisely what risks are associated with them"* and *"the risks associated with using pharmacy medicines affect me personally".* There was strong agreement (>70%) with 11 statements and strong disagreement (>70%) with two statements (Table 2). Figure 2 shows the mean agreement for the general risk statement followed by each statement (ordered from most agreement at the bottom to least agreement at the top).

Identifying risk components: Factor analysis

Two statements, "*Pharmacy medicines can be addictive"* and *"Pharmacy medicines that used to be available on prescription have greater risk than medicines that have been available with our prescription for many years"* showed correlation < 0.2 with other items were and were excluded from the factor analysis. The factor analysis of the remaining 21 statements produced a KMO measure of sampling adequacy of 0.781 which is considered good and Bartlett test of sphericity was $p<0.001$, indicating factor analysis was appropriate. The eigenvalue >1 rule and the scree plot indicated that six factors should be extracted totalling 58.2% of the variance using a varimax rotation.

Table 2 shows the six identified factors and their loadings, with loadings <0.4 suppressed for clarity. The first factor (*Personal Acceptance*) contributed 16.5% of the variance and consisted of items around acceptance, benefit and comfort with Pharmacy medicines. The second factor (*General risk perception*) consisted of statements relating to a general view of risk and

contributed an additional 15.9% of the variance. The third factor (*Populations and behavioural risk factors*) contributed 8.3% of the variance and contained statements relating to risk in specific populations such as children and pregnant women. The fourth factor (*Adherence*) (i.e. adherence to giving information) was mainly related to using information to manage risk and contributed 6.7% of the variance. The fifth factor (D*enial of risk*) contributed to 6.0% of variance and the sixth factor (*Individual- and population-risk*) contributed the final 4.9% of the total variance.

Do individual characteristics predict risk perception?

Univariate analyses of the relationship between demographic variables and factor scores was undertaken. No significant gender difference ($p>0.05$) was found. Older respondents were significantly more likely to agree (equating to lower risk perception) with the statements associated with three factors: *General risk* ($p=0.004$), *Population and behaviour risk factors* ($p<0.001$), *Adherence* ($p=0.033$). Respondents with post-school education showed significantly higher risk perception for *Adherence* ($p=0.001$) compared with those with no formal or only school level education, but had lower scores (lower risk perception) for *General Risk Perception* ($p=0.02$) and *Individual- and population-risk* ($p=0.03$). Those married/living with partner showed significantly lower scores for *Personal Acceptance* ($p=0.016$).

For health status, respondents reporting good/very good/excellent status compared with fair/poor were significantly more likely to agree (lower risk perception) with the statements associated with the factors: *Personal Acceptance* ($p=0.02$) and *Populations and Behaviour Risk Factors* ($p=0.002$), and to disagree (higher risk perception) with statements associated with *Denial ($p=0.033$)*.

Six multiple linear regression was used to investigate the combined effects of these demographic variables in predicting each of the six factor scores (Table 3). Age was an important predictor for *General Risk Perception*, *Populations and Behaviour Risk Factors*, *Denial* and *Individual- and Population-risk* with older age indicating greater agreement/ lower risk perception (as indicated by the negative coefficients). Gender was only important for *Adherence*, with females indicating more agreement i.e. higher risk perception. Education was important for *General Risk Perception* and *Individual- and Population-risk* with greater education levels associated with greater agreement/higher risk perception. Health status was significant for *Personal Acceptance* and *Denial* with those in good/very good/excellent health indicating more agreement. In each case, the R-square was low (<5%) but the ANOVA p-value was significant indicating that the demographics explained a low, but statistically significant, percentage of variability in the factor scores.

Does risk perception predict behaviour (information giving)?

Respondents with overall low risk perception were significantly more likely to have disclosed information during their last pharmacy consultation than those with higher risk perception: 41.2% versus 33% (p=0.032). No statistically significant differences in factor scores occurred between respondents who disclosed and those that did not.

Does risk perception predict behavioural determinants (TPB variables)?

Respondents who perceived NPMs to be associated with low risk had significantly higher attitude (p=0.003) and perceived behavioural control scores (p=0.01) regarding giving information to medicine counter assistants (MCAs). This means that respondents who were categorised as “low risk” believed that giving information would achieve better outcomes.

There was some indication that respondents' with low risk perception had higher intention to disclose information than those who perceived NPMs to be of high risk (p=0.05).

DISCUSSION

Main results

This is the first theoretically-underpinned study to explore public risk perception of NPMs and information disclosure. The results showed that, in general, NPMs were perceived to be associated with low risk and that low risk perception was associated with higher tendency to disclose information thus disproving our hypothesis. In a study about patient information leaflets, people who were more worried about adverse effects were less likely to read the leaflet. This fits with the idea that high risk perception is linked to a lack of engagement with information, which reflects our finding that low risk perception was associated with higher tendency to disclose information [24]. Another study found low risk perception may be associated with higher tendency to disclose information due to variations in 'regulatory' focus, i.e. the extent to which individuals seek to promote positive or prevent negative comments. In promotion focus, they are more prepared to take risks and to engage in promotion activities such as giving information [25].

Limitations/strengths

These data were collected in 2008 and have undergone substantial analysis and iterations. Whilst a survey of *general* risk perception of NPMs in the UK was conducted in 2013 [26], there are no published studies of in-depth risk perception as reported in the current study. As such we believe the results are important and provide a unique contribution to existing knowledge. Furthermore,in the intervening period, no major changes have occurred with NPMs in Scotland/UK in general, although tighter restrictions have been introduced for some medicines associated with misuse e.g. pseudoephedrine (https://www.gov.uk/drug-safety-

update/pseudoephedrine-and-ephedrine-update-on-managing-risk-of-misuse), the age limit was raised limit for cough remedies for children (https://www.gov.uk/drug-safety-update/over-the-counter-cough-and-cold-medicines-for-children) and diclofenac was reclassified to Prescription Only Medicine status because of new evidence regarding cardiovascular toxicity (https://www.gov.uk/government/news/diclofenac-tablets-now-only-available-as-a-prescription-medicine).

This current study was conducted in Scotland and few respondents were from ethnic minorities thus the effect of ethnicity could not be explored, but has been shown previously to influence risk perception of prescription medicines [18]. A 2:1 female: male sampling strategy was used (to reflect the higher rates of pharmacy and medicine use by females) and generated more female than male respondents. Furthermore, respondents were more likely to be older and to be married or living with someone. These characteristics mean that these results might not be generalisable to individuals from ethnic minorities, people who are living alone, or younger individuals. Bias may have been introduced into the sample through the use of the electoral register, however, it was the most inclusive method available for this survey. The study had sufficient power (based upon the derived sample size of 927) to conduct the factor analysis which generated six factors and explained 58% of the variation.

Comparison with literature

A much higher proportion of respondents (71.4%) in our study agreed that there was "no risk with pharmacy medicines" compared with an earlier survey which showed that only 47.4% of respondents agreed/strongly agreed that *"non-prescription medicines are totally safe to use"* [27]. Our results suggest that individual respondents' perceive themselves to be at less risk from NPMs compared with the wider population. This finding is congruent with an earlier

study suggesting that consumers were critical of the public's ability to self-medicate safely and appropriately using NPMs [28]. All NPMs were treated as one group in this current study. Slovic et al [18] included four medicines available in non-prescription form and explored differences in risk perceptions between them. Other studies have compared risk perception of NPMs versus prescription only medicines but have demonstrated conflicting results, with some showing public perception of risk to be greater with POMs compared with NPMs [11], whilst others report the converse [12]. An earlier study of individuals who used a NPM for the relief of hay-fever (terfenadine) which was subsequently reclassified back to prescription medicine status because of adverse effects, expressed concern about the previously unknown risks with the use of the drug [28]. Their risk perceptions of NPMs also changed as a result of the reclassification of this medicine.

Implications for policy, practice and research

These results highlight a need to increase public awareness regarding the use of NPMs as well as the importance of sharing information during NPM consultations. Pharmacy personnel need to actively seek relevant information from consumers to inform their decisions regarding the appropriate treatment and research is ongoing to explore strategies which influence both service provider and user behaviour during these consultations.

CONCLUSION

There is general low public risk perception of NPMs. Interventions that target risk perception are unlikely to enhance the safe and effective supply of these medicines because they will not enhance information disclosure during consultations. Alternative strategies are needed to enhance the public's health literacy regarding these medicines and the importance of information disclosure to maximise their safe and effective use.

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Table 1: Respondent demographics n (%)

		N = 927
Gender		(n = 895)
	Male	241 (27)
	Female	654 (73)
Marital status		(n = 894)
	Single	134 (15)
	Married/living with partner	612 (69)
	Divorced/separated	67 (8)
	Widowed	81 (9)
Highest educational qualification		(n = 914)
	No formal education	162 (18)
	School level	274 (30)
	post School (non-university)	102 (11)
	University degree	229 (25)
	Other	134 (15)
Ethnic group		(n = 914)
	White	903 (99)
	Other	11 (1)
Health status		(n = 913)
	Excellent	107 (12)
	Very good	357 (39)
	Good	300 (33)
	fair/poor	149 (16)
Age (years)		(n = 892)
	Mean (SD)	53.2 (16.1)

Table 2: Pharmacy Medicines, mean agreement of risk perception and factor loadings

			Factor Loadings using Varimax Rotation					
			1	*2*	*3*	*4*	*5*	*6*
Question	**Total N**	**Mean Agreement****	***Personal Acceptance***	***Medicines' Risk***	***Population and behaviour risk factors***	***Adherence***	***Denial***	***Individual- and population-risk***
In general how much risk do you think there is when using pharmacy medicines	829	3.23						
The risks associated with using pharmacy medicines are acceptable to me	828	2.83	0.848					
I can deal with the risks of using pharmacy medicines	833	2.87	0.822					
I feel comfortable with the level of risk associated with using pharmacy medicines	**835**	**2.60**	**0.812**					
Using pharmacy medicines is beneficial to me	**841**	**2.49**	**0.622**					
It is up to me whether I put myself at risk due to using pharmacy medicines	**834**	**2.72**	**0.425**	**0.435**				
People who use pharmacy medicines know precisely what risks are associated with them	834	4.27	0.423				0.532	
There is more risk involved in using pharmacy medicine than there was 10 years ago	**829**	**4.59**		**0.665**				
Using pharmacy medicines could harm people	827	3.66		0.653				
The risks associated with using pharmacy medicines may not be understood until much later	835	3.36		0.633				
The risks associated with using pharmacy medicines are likely to be fatal	**831**	**5.12**		**0.594**				

Everyone who uses a pharmacy medicine could be at risk from these medicines	831	3.60		0.407				0.598
Children are at greater risk than adults when using pharmacy medicines	836	2.92			0.853			
Pregnant women are at greater risk when using pharmacy medicines	**834**	**2.62**			0.838			
Using a pharmacy medicine and driving can be risky	**868**	**2.59**			**0.565**			
Drinking alcohol whilst using pharmacy medicines can be risky	**845**	**1.90**			0.550	**0.457**		
When using pharmacy medicines, I always use the recommended dose	**842**	**1.56**				**0.757**		
Pharmacy medicines are less risky if you follow the instructions when using them	**838**	**1.68**				**0.629**		
If I do not follow the instructions when using pharmacy medicines I will be putting myself at risk of harm	**843**	**1.95**				**0.624**		
It is not possible to overdose with pharmacy medicines*	**836**	**1.77**					**0.763**	
There are no risks associated with using pharmacy medicines*	**826**	**2.64**					**0.692**	
The risks associated with using pharmacy medicines affect me personally	817	4.14						0.875
Pharmacy medicines can be addictive	832	3.00	Not included in factor analysis					
Pharmacy medicines that used to be available on prescription have greater risk than medicines that have been available without a prescription for many years	855	3.76	Not included in factor analysis					

*Reverse coded to enable comparable interpretation

** Agreement: Strongly agree (1) to Strongly Disagree (7)

Bold indicates statements with > 70% agreement/disagreement

Table 3: Regression coefficients (SE) for models examining the predictive ability of demographic factors on each factor score

	Factor 1 *Personal Acceptance*	Factor 2 General Risk Perception	Factor 3 Population and Behaviour Risk Factors	Factor 4 Adherence	Factor 5 Denial	Factor 6 Individual and Population Risk
N	802	805	826	830	814	812
R-square	0.007	0.022	0.03	0.012	0.008	0.013
ANOVA F	5.53	9.10	25.7			
p-value	0.019	<0.001	<0.001	4.96 0.007	6.93 0.009	5.21 0.006
Constant	3.19 (0.10)	4.41 (0.14)	3.21 (0.15)	2.27 (0.16)	3.09 (0.08)	4.46 (0.21)
Gender						
Female				-0.155 (0.07)		
Age						
per year		-0.008 (0.08)	-0.014 (0.003)	-0.004 (0.002)		-0.008 (0.11)
Health						
Good/very good/excellent	-0.249 (0.11)				-0.235 (0.09)	
Education						
Post school		-0.238 (0.002)				-0.29 (0.004)

NB: Marital status was not selected by any model so is not included in this table

FIGURES

Figure 1: Theory of Planned Behaviour

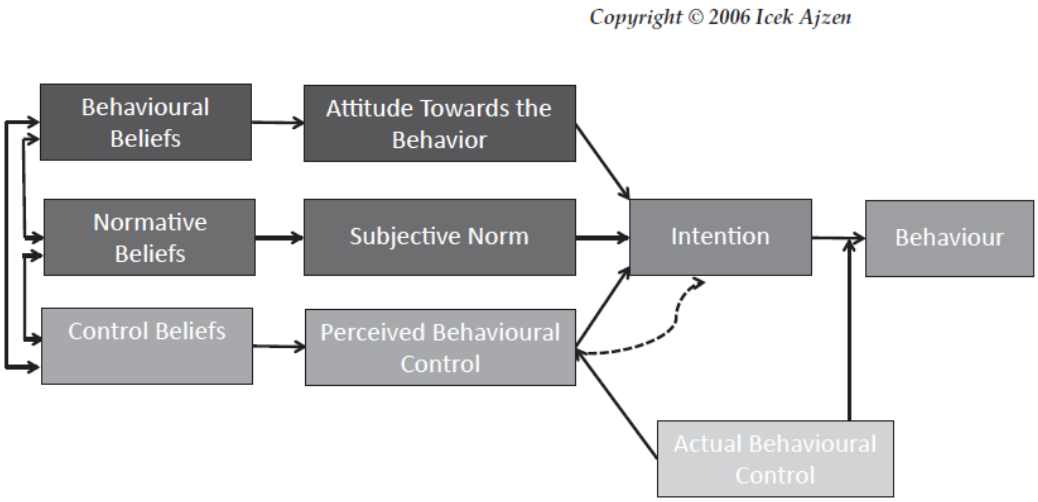
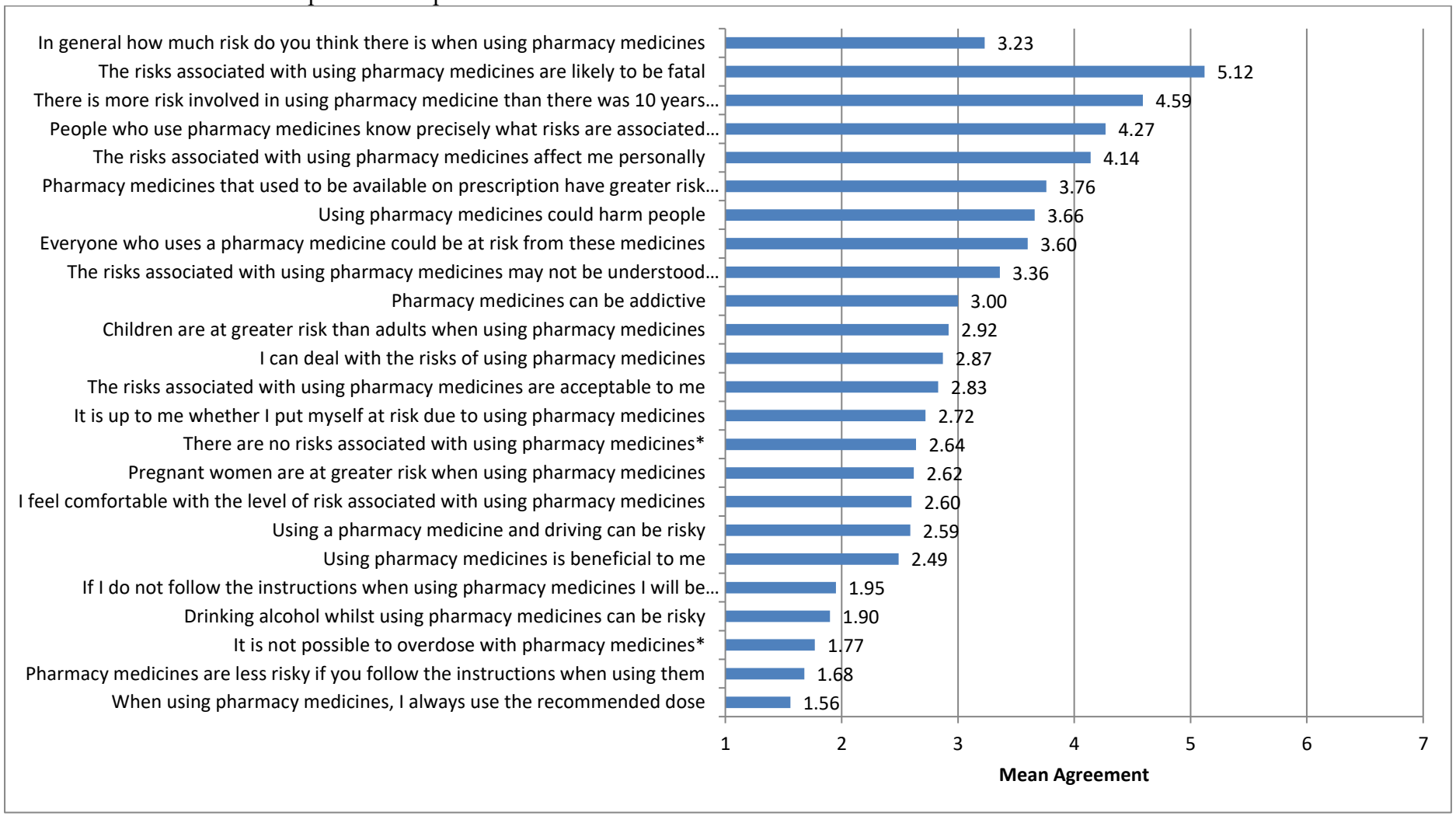


Figure 2 Respondents' mean agreement with risk perception statements (1 = strongly agree to 7 strongly disagree)
*Reverse coded to enable comparable interpretation



*Reverse coded to enable comparable interpretation